UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,084	07/05/2001	Nelson R. Holcomb	10010372-1	5860

7590 09/20/2002

AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P.O. Box 7599
Loveland, CO 80537-0599

EXAMINER
CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/900,084	Holcomb
Examiner	**Art Unit**
Arun Chakrabarti	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- *Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.*
- *If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.*
- *If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.*
- *Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).*
- *Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).*

Status

1) ☒ *Responsive to communication(s) filed on 7/5/01, 8/13/01 and 9/18/01 .*

2a) ☐ *This action is* **FINAL.** 2b) ☒ *This action is non-final.*

3) ☐ *Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.*

Disposition of Claims

4) ☒ *Claim(s) 20-35 and 50 is/are pending in the application.*

4a) *Of the above, claim(s) _____ is/are withdrawn from consideration.*

5) ☐ *Claim(s) _____ is/are allowed.*

6) ☒ *Claim(s) 20-35 and 50 is/are rejected.*

7) ☐ *Claim(s) _____ is/are objected to.*

8) ☐ *Claims _____ are subject to restriction and/or election requirement.*

Application Papers

9) ☐ *The specification is objected to by the Examiner.*

10) ☐ *The drawing(s) filed on _____ is/are objected to by the Examiner.*

11) ☐ *The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.*

12) ☐ *The oath or declaration is objected to by the Examiner.*

Priority under 35 U.S.C. § 119

13) ☐ *Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).*

a) ☐ *All* b) ☐ *Some** c) ☐ *None of:*

1. ☐ *Certified copies of the priority documents have been received.*
2. ☐ *Certified copies of the priority documents have been received in Application No. _____ .*
3. ☐ *Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).*

**See the attached detailed Office action for a list of the certified copies not received.*

14) ☐ *Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).*

Attachment(s)

15) ☒ *Notice of References Cited (PTO-892)*
16) ☐ *Notice of Draftsperson's Patent Drawing Review (PTO-948)*
17) ☐ *Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____*
18) ☐ *Interview Summary (PTO-413) Paper No(s). _____*
19) ☐ *Notice of Informal Patent Application (PTO-152)*
20) ☐ *Other:*

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-19, 36-49, and 51-57, drawn to buffer composition, classified in class 252, subclass 364.

   II. Claims 20-35, and 50, drawn to method of nucleic acid hybridization, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons: Inventions of Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product of Group I can be used in the nucleic acid hybridization of Group II or can be used in the PCR reaction or in any suitable enzymatic reaction.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Gordon Stewart on December 12, 2001 a provisional election was made with traverse to prosecute the invention of Group II, claims 20-35 and 50. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-19, 36-49 and 51-57 are withdrawn from further consideration by the examiner, 37 CAR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CAR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CAR 1.48(b) and by the fee required under 37 CAR 1.17(I).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32, 34, and 35 are rejected over the recitation of the phrase, "location". It is not clear if a location on the microarray is claimed or in the laboratory is claimed or both. The metes and bounds of the claims are vague and indefinite.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 20-23, 25, 28, and 31-32 are rejected under 35 U.S.C. 102 (a) as being anticipated by Goldberg et al. (U.S. Patent 6,203,989 B1) (March 20, 2001).

Goldberg et al teach a method of hybridizing a microarray of oligonucleotides bound to an adsorbed polymer surface on a siliceous substrate with a nucleic acid material (Abstract, Column 3, lines 33-39, and Column 14, lines 13-30) comprising the steps of:

incubating the nucleic acid material with the microarray of oligonucleotides on the adsorbed polymer surface in a hybridization solution at a hybridization temperature ranging from about 55 degree centigrade to about 70 degree centigrade so as to hybridize the nucleic acid material,

wherein the hybridization solution comprises a buffer composition that comprises a pH within a range of pH 6.4 to 7.5, a non-chelating buffering agent selected from 2-[N-

morpholino]ethanesulfonic acid (MES) that maintains the pH within the pH range, and a monovalent cation selected from NaCl in a concentration ranging from about 0.01 M to about 2.0 M (Column 14, lines 13-41 and Column 10, lines 6-17).

Goldberg et al. teach a method, wherein in the step of incubating, the buffer composition further comprises a chelating agent EDTA (Examples 1 and 2).

Goldberg et al. teach a method, before the step of incubating, further comprising the step of combining the nucleic acid material with the buffer composition (Example 2, Chip Pre-treatment solution).

Goldberg et al. teach a method, after the step of incubating, further comprising the step of interrogating the hybridized microarray at a first location (Example 2, Tables 1-2).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 20-25, 28, and 31-35 are rejected under 35 U.S.C. 103 (a) over Goldberg et al. (U.S. Patent 6,203,989 B1) (March 20, 2001) in view of Reynolds et al. (U.S. Patent 6,316,608 B1) (November 13, 2001).

Goldberg et al teach the method of claims 20-22, 25, 28, and 31-32 as described above.

Goldberg et al do not teach a method, wherein the adsorbed polymer surface comprises a polycationic polymer polyethylenediamine.

Reynolds et al. teach a method, wherein the adsorbed polymer surface comprises a polycationic polymer polyethylenediamine (Column 5, lines 22-49).

Goldberg et al do not teach a method, further comprising the step of transmitting data representing a result of the interrogation and receiving the same at a second location remote from the first location.

Reynolds et al. teach a method, further comprising the step of transmitting data representing a result of the interrogation and receiving the same at a second location remote from the first location (Example 2, Column 11, lines 14-20).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein the adsorbed polymer surface comprises a polycationic polymer polyethylenediamine further comprising the step of

transmitting data representing a result of the interrogation and receiving the same at a second location remote from the first location of Reynolds et al. in the nucleic acid hybridization buffer of Goldberg et al since Reynolds et al state, "One advantage of the present invention is that it reduces the variation in hybridization signals from element to element (Column 7, lines 37-39)". Moreover, Goldberg et al provide motivation as Goldberg et al state, "In another embodiment, an array of different nucleic acid probes immobilized on a surface, each having a defined sequence and location on the surface, may be used in the assays, thus permitting screening and detection of binding of a large number of nucleic acids (Abstract, last sentence)". An ordinary practitioner would have been strongly motivated by employing the simple scientific reasoning as well as motivations provided by Reynolds et al and Goldberg et al. to combine and substitute a method, wherein the adsorbed polymer surface comprises a polycationic polymer polyethylenediamine further comprising the step of transmitting data representing a result of the interrogation and receiving the same at a second location remote from the first location of Reynolds et al. in the nucleic acid hybridization buffer of Goldberg et al. in order to improve the nucleic acid hybridization and in order to achieve the express advantages, as noted by Reynolds et al., of a method that can be used to reduce the variation in hybridization signals from element to element and also in order to achieve the express advantages, as noted by Goldberg et al., of an array of different nucleic acid probes immobilized on a surface, each having a defined sequence and location on the surface, thus permitting screening and detection of binding of a large number of nucleic acids.

12. Claims 20-22, 25-28, and 31-32 are rejected under 35 U.S.C. 103 (a) over Goldberg et al. (U.S. Patent 6,203,989 B1) (March 20, 2001) in view of Cohen (U.S. Patent 6,322,989 B1) (November 27, 2001).

Goldberg et al teach the method of claims 20-22, 25, 28, and 31-32 as described above.

Goldberg et al do not teach a method, wherein the buffer composition further comprises an ionic surfactant SDS at a concentration ranging from about 0.01% to about 0.2% (w/v).

Cohen teaches a method, wherein the buffer composition further comprises an ionic surfactant SDS at a concentration ranging from about 0.01% to about 0.2% (w/v) (Column 19, lines 46-51 and Column 20, lines 1-5).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein the buffer composition further comprises an ionic surfactant SDS at a concentration ranging from about 0.01% to about 0.2% (w/v) in the nucleic acid hybridization buffer of Goldberg et al since Cohen states, "Those of skill will be aware that it will often be advantageous in nucleic acid hybridizations to include detergents (e.g., sodium dodecyl sulfate), chelating agents (e.g., EDTA) or other reagents in the hybridization or wash solutions (Column 19, lines 46-51)". Moreover, Goldberg et al provide motivation as Goldberg et al state, "In another embodiment, an array of different nucleic acid probes immobilized on a surface, each having a defined sequence and location on the surface, may be used in the assays, thus permitting screening and detection of binding of a large number of nucleic acids (Abstract, last sentence)". An ordinary practitioner would have been strongly

motivated by employing the simple scientific reasoning as well as motivations provided by Cohen and Goldberg et al. to combine and substitute a method, wherein the buffer composition further comprises an ionic surfactant SDS at a concentration ranging from about 0.01% to about 0.2% (w/v) in the nucleic acid hybridization buffer of Goldberg et al. in order to improve the nucleic acid hybridization and in order to achieve the express advantages, as noted by Cohen., of a method that is often advantageous in nucleic acid hybridizations to include detergents (e.g., sodium dodecyl sulfate), chelating agents (e.g., EDTA) or other reagents in the hybridization or wash solutions and also in order to achieve the express advantages, as noted by Goldberg et al., of an array of different nucleic acid probes immobilized on a surface, each having a defined sequence and location on the surface, thus permitting screening and detection of binding of a large number of nucleic acids.

13. Claims 20-22, and 25-32 are rejected under 35 U.S.C. 103 (a) over Goldberg et al. (U.S. Patent 6,203,989 B1) (March 20, 2001) in view of Cohen (U.S. Patent 6,322,989 B1) (November 27, 2001) further in view of McDonough et al. (U.S. Patent 6,252,059 B1) (June 26, 2001).

Goldberg et al in view of Cohen teach the method of claims 20-22, 25-28, and 31-32 as described above.

Goldberg et al do not teach a method, wherein the buffer composition further comprises a monovalent cation LiCl at a concentration greater than or equal to 300 mM.

McDonough et al. teach a method, wherein the buffer composition further comprises a monovalent cation LiCl at a concentration greater than or equal to 300 mM.(Column 4, lines 2-10, and Column 8, lines 15-50).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein the buffer composition buffer composition further comprises a monovalent cation LiCl at a concentration greater than or equal to 300 mM of McDonough et al in the method of Goldberg et al. in view of Cohen since McDonough et al state, "In a related aspect, the invention features the formation of nucleic acid hybrids formed by the hybridization of the probes of this invention with target nucleic acids under stringent hybridization conditions. Stringent hybridization conditions involve the use of 0.6 M LiCl at 60 degree centigrade. The hybrids are useful because they allow the specific detection of viral nucleic acid (Column 4, lines 3-10)". Moreover, Goldberg et al provide motivation as Goldberg et al state, "In another embodiment, an array of different nucleic acid probes immobilized on a surface, each having a defined sequence and location on the surface, may be used in the assays, thus permitting screening and detection of binding of a large number of nucleic acids (Abstract, last sentence)". An ordinary practitioner would have been strongly motivated by employing the simple scientific reasoning as well as motivations provided by McDonough et al and Goldberg et al. to combine and substitute a method, wherein the buffer composition buffer composition further comprises a monovalent cation LiCl at a concentration greater than or equal to 300 mM of McDonough et al in the method of Goldberg et al. in view of

Cohen in order to improve the nucleic acid hybridization and in order to achieve the express advantages, as noted by McDonough et al., of a method that provides nucleic acid hybrids made under stringent conditions that are useful because they allow the specific detection of viral nucleic acid and also in order to achieve the express advantages, as noted by Goldberg et al., of an array of different nucleic acid probes immobilized on a surface, each having a defined sequence and location on the surface, thus permitting screening and detection of binding of a large number of nucleic acids.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti , Ph. D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun kr. Chakrabarti

Arun Chakrabarti,

Patent Examiner

December 13, 2001

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600